Remarks

Claims 1-52 are currently pending in the application.

Restriction has been required under 35 U.S.C. § 121 to one of the following groups:

Group I, claims 1-20, drawn to a composition comprising a polyethylenimine-sterol conjugate, allegedly classified in class 514, subclass 182+;

Group II, claims 21-40, drawn to a complex comprising a nucleic acid and a polyethylenimine-sterol conjugate, allegedly classified in class 514, subclass 2+;

Group III, claims 41-51, drawn to a process of making a polyethylenimine-sterol conjugate, allegedly classified in class 552, subclass 544; and

Group IV, claim 52, drawn to a method of delivering a nucleic acid into a mammalian cell, allegedly classified in class 514, subclass 2+.

For the purpose of providing a complete response to the present Office Action, Applicants elect Group II, claims 21-40. Applicants respectfully traverse the restriction requirement for the reasons set out below.

Under MPEP § 803 there are two criteria that must both be met before a restriction requirement is proper: (1) The inventions must be independent or distinct as claimed, and (2) there must be

a serious burden on the examiner if restriction is not required. The initial burden is on the examiner to provide reasons with respect to both of these requirements. MPEP § 803.

The Office Action alleged that Group I and Group II are related as a product and a process of use. This allegation is incorrect. Group I and Group II both relate to products. Group I is drawn to a composition comprising a polyethylenimine-sterol conjugate, which may be used for forming a complex with a nucleic acid for delivery into a mammalian cell. Group II is drawn to a complex comprising a nucleic acid and the polyethylenimine-sterol conjugate of Group I. The only difference between the products of Group I and Group II is the presence (Group II) or absence (Group I) of a nucleic acid. Therefore, Group I and Group II are drawn to related products. The Office Action alleged that Group I and Group II are identically classified. It appears that a search for Group I would be coextensive with a search for Group II. The Office Action failed to establish that Group I and Group II are either independent or distinct and further failed to establish that there would be a serious burden on the examiner if restriction were not required. Therefore, the Office Action failed to establish a *prima facie* case that restriction is proper. Accordingly, withdrawal of the restriction requirement with respect to Group I and Group II is respectfully requested.

The Office Action stated that Group III and Group IV are related as a process of making a product and a process of using the product made. This is correct, however, the Office Action did not apply the correct test for determining whether such processes are distinct. MPEP § 805.05(I) states that where, as here, an application contains claims to a product, claims to a process specially adapted for making the product, and claims to a process of using the product, the applicant may be required to elect either (A) the product and process of making it or (B) the process of using. If, however, the examiner cannot make a showing of distinctness between the process of using and the product, "restriction cannot be required."

A condition of applying the above-stated regulation is that the claims to the process of making the product must be specially adapted therefor. That is, the product and the process of making it must not be patentably distinct, as defined in MPEP § 806.05(f). This section states that a process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process *as claimed* is not an obvious process of making the product and the process *as claimed* can be used to make another materially different product; or (B) that the product *as claimed* can be made by another materially different process. The Office Action failed to present

reasons with respect to either of (A) or (B). The Office Action did state: "Inventions I/II and III/IV are unrelated because they are drawn to different scopes of polyethylenimine sterol conjugates." *Unrelatedness* means independent, i.e., not dependent. Group III is drawn to methods of making the conjugates of Group I, and Group IV is drawn to a method of using the conjugates of Group I or the complexes of Group II. Therefore, Group III and Group IV are clearly related to Group I and Group II. The Office Action provided no reasons that would relate to distinctness of these groups. Therefore, a *prima facie* case of distinctness of the process of making and the product made was not established. Hence, the process of Group III should be considered to be specially adapted for making the product claimed. With this condition met, the rest of the test can proceed and is addressed in the next paragraph.

The next question is whether distinctness of the product and the process of using has been established. MPEP § 806.05(h) states that a product a process of using the product can be shown to be distinct inventions if either of both of the following can be shown: (A) the process of using *as claimed* can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. The Office Action stated, "in the instant case the process of using, i.e., for

delivering of a nucleic acid into a mammalian cell, can be practiced with another materially different product." This statement fails to address the relevant test, because the issue is whether (emphasis added) "the process of using *as claimed* can be practiced with another materially different product." The process *as claimed* is found in claim 52, which states that the nucleic acid is mixed with an L-shaped, T-shaped, or LT-shaped linear polyethylenimine sterol conjugate to result in a complex and then contacting a mammalian cell with the complex. Substituting a materially different product, as suggested in the Office Action, would not result in practicing the process *as claimed.* In other words, one cannot substitute a materially different product, because the resulting process would not be the process *as claimed.* The Office Action did not address the (B) part of the test, i.e., whether the product *as claimed* can be used in a materially different process. Therefore, the Office Action failed to make a showing of distinctness between the process of using and the product. Hence, "restriction cannot be required." MPEP § 806.05(I). Accordingly, withdrawal of the restriction requirement is respectfully requested.

Applicants respectfully submit that no *prima facie* case of serious burden has been shown. Moreover, Applicants respectfully submit that there would be no serious burden on the examiner to

examine the present application, regardless of whether or not a *prima facie* case of serious burden has been shown. For this reason, as well, withdrawal of the restriction requirement is respectfully requested.

The Office Action further required, under 35 U.S.C. § 121, election of a single disclosed species. Applicants respectfully traverse this requirement, as well. To provide a complete reply to this requirement, Applicants respectfully elect claims drawn to polyethylenimine-cholesterol conjugates wherein these conjugates are in the T configuration. Claims readable on this species are claims 8-14, 28-34, 44-48, and 52.

In conclusion, Applicants respectfully request that the restriction requirement be withdrawn and the application be examined as a unitary invention.

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Respectfully submitted,

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